# EXHIBIT 34

# Expert Rebuttal by Susan Schwartz McDonald, Ph.D. on a Survey Conducted for Plaintiffs by Annie Steinberg, MD

October, 2019



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#### I. Introduction

#### A. Scope of Testimony and Summary of Opinions

I was retained by Morgan Lewis as an expert witness on behalf of Defendant in *Monique Russell et al. v Educational Commission for Foreign Medical Graduates*, class action litigation which has been brought in the Eastern District of Pennsylvania. Specifically, my charge is to offer rebuttal testimony to a survey conducted on behalf of Plaintiffs by Dr. Annie Steinberg, a psychiatrist whose survey of putative class members purports to assess harm suffered by Plaintiffs as a result of their experiences under the care of "Dr. Akoda". I note that my testimony is not offered in rebuttal to any allegations regarding Dr. Akoda's credentials or the circumstances under which he practiced medicine. My testimony as a survey methodology expert is focused exclusively on the *validity of the survey assessment* made by Dr. Steinberg, and its meaningfulness as a vehicle for measuring psychological harm and other life consequences experienced by Plaintiffs, either as individuals or as a class. My testimony also makes no assumptions about the legal purpose or relevance of Dr. Steinberg's data and conclusions.

I base my opinions on my graduate training in the social sciences, my professional expertise in the field of survey science, and my applied experience as a research professional who has been chief executive of a highly respected, century-old marketing and opinion research firm, and has authored and supervised thousands of complex surveys relied on by corporations, government agencies, and courts over a span of nearly four decades. Also relevant to this rebuttal analysis is my expertise in *qualitative* research, having conducted many thousands of qualitative interviews in my career and co-authored the field's first standard text on qualitative interview techniques.

Based on my expertise in survey design, implementation, analysis, and interpretation, I have concluded that Dr. Steinberg's survey is not simply amateurish; it is so methodologically deficient and so biasing as to lack validity as a survey measurement tool. Due to numerous disabling methodological flaws, none of the statistics generated by this survey can be taken at face value or serve as the basis for conclusions, even with a confidence interval applied.

#### B. Professional Credentials and Compensation

I am President and CEO of NAXION, a century-old marketing research and consulting organization that advises companies on product development, brand strategy, and other strategic marketing activities. As an expert in marketing and opinion research, I consult to companies on a variety of strategic issues including brand health, opportunity assessment, innovation, commercialization strategy, and lifecycle management. My marketing and research experience encompass assignments designed to improve customer experience and strengthen brand reputation, as well as develop and commercialize new market offerings in a number of industries – particularly Healthcare, Consumer products, and Financial services.

Survey research is a principal tool in a large number of these engagements, and I am relied on by clients and colleagues for my expertise in designing and developing surveys with complex

objectives, many of which are used to measure opinions and behaviors within challenging or sensitive populations. Throughout my career, I have personally designed and conducted thousands of surveys, many of them in the service of developing new products, optimizing product configuration, projecting demand or measuring public health consequences of product usage. I have also consulted and testified frequently on the application and interpretation of survey research to adjudicate claims under the Lanham Act (as well as decide patent claims) and my survey work has been utilized by government agencies like FDA and FTC, as well as USPTO. I am quite familiar with the specialized issues associated with collecting data on patient experience with diagnosis and disease progression, interactions with healthcare professionals, and recollections of their healthcare "journey." Throughout my career, I have conducted hundreds of surveys with healthcare consumers and patients of all kinds (including some who have received psychiatric diagnoses). I have also worked on the development and application of survey tools designed to measure patient-reported outcomes (PROs).

Although my professional focus is on commercial application, not academics, I make regular podium appearances and have lectured extensively on research methodology and marketing at major universities (e.g., University of Pennsylvania and Princeton University), commercial organizations, and industry-training programs sponsored by major professional organizations—for instance, the Council of American Survey Research Organizations (CASRO), the Pharmaceutical Marketing Research Group (PMRG), Healthcare Marketing and Communications Council (HMC), and the Advertising Research Foundation (ARF). I have also served as Chair of the Board of Directors of CASRO, the trade association of the US marketing and survey-research industry, recently renamed The Insights Association. In my decade of CASRO board service, I was actively involved in the development of standards for survey research, both ethical and technical. Currently, I am a trustee of The Wistar Institute, the world's second oldest incubator of biomedical research discoveries, as well as President of the Board of The Chamber Orchestra of Philadelphia.

My professional marketing career has been spent at NAXION, known until 2014 as National Analysts Worldwide, and previously a division of the global commercial and technology consulting firm Booz•Allen & Hamilton, where I was a partner and vice president. My tenure at Booz•Allen included a period during which I served as the leader of that firm's worldwide pharmaceutical-industry practice. NAXION traces its roots directly to the world's first business intelligence unit and progenitor of the survey research discipline (1911). Some of the nation's first commercial and government sponsored surveys were conducted by National Analysts (and its predecessor company, Curtis Publishing) and the firm is known to have shaped the opinion research and marketing research fields through the development of probability sampling and other landmark survey techniques, as well as the genesis of the focus group. In 1992, National Analysts became an independent entity, under my co-ownership, and is now an Employee-Owned Stock Ownership Corporation (ESOP) of which I am majority shareholder. Renamed NAXION, the firm retains the same ownership and management structure, and the same corporate mission. It has consistently been listed as one of the AMA "Top 40" market research firms in the US.

I received my BA degree magna cum laude, Phi Beta Kappa, from Smith College, and my MA and doctoral degrees from the University of Pennsylvania's Annenberg School for Communication, where my studies were concentrated in the field of social psychology and communications theory. I am the author of a text on market research and of numerous publications and speeches on marketing and market research methodology. A complete copy of my vitae along with a list of publications authored in the past ten years, and testimony and depositions taken in the past five years is included in Exhibit 1.

I am being compensated for my work in this case at my customary fee of \$675 per hour. My compensation is in no way contingent on the outcome of the case.

#### C. Basis for my Opinions

In order to form my opinions, I have reviewed the following documents and materials:

- Complaint in Russell et al. v. ECFMG
- Answer in Russell et al. v. ECFMG
- Report of Annie Steinberg, MD, with Attached Questionnaire
- CV of Annie Steinberg, MD
- List of Testimony by Annie Steinberg, MD
- Rough Transcript of Deposition of Annie Steinberg, MD (10/10/2019)
- Emails0003-0004 from Exhibit 4 to the Deposition of Annie Steinberg, MD (10/10/2019)
- "Akoda Questionnaire Blank" (provided by Plaintiffs' counsel)
- "Akoda Summary Statements" (provided by Plaintiffs' counsel)

I note that, as of this writing, I have not been provided with an electronic database for the survey and have therefore not been able to manipulate or query the data to confirm Dr. Steinberg's limited statistical analyses, or to perform any of my own. Her claim not to have such a database at her disposal is highly unusual insofar as survey programs produce readily manipulated databases as a matter of course. (Manual inspection of individual data files does not lend itself to statistical tabulations or efficient review.) I have also not seen actual screen shots of the survey or had an opportunity to gain direct experience with the survey programming. Especially in light of my inability to access an electronic database at this moment of submission, I reserve the right to add or amend my rebuttal report, as relevant, if additional data, or other survey documents of any kind, are made available to me.

#### II. Survey Definition and Methodological Requirements

#### A. What is a 'Survey'?

As a measurement tool of the social or behavioral sciences, survey research is guided by a set of principles and long-established best practices that aspire to justify the term "survey science". If you want to learn something about a large number of people and to feel confident that you've accurately measured what you set out to measure, it's not enough to ask them the same set of questions and then count the answers. Experience in other forms of research (e.g., experimental or clinical trial design, or proficient use of existing diagnostic tools to conduct clinical research) does not generalize to expertise in survey measurement without specific survey training.

A survey collects data from a representative subset based on the premise that when properly sampled and correctly interviewed, that small set of individuals can enable us to draw accurate conclusions about the broader universe. Whether conducted on-line (the majority), by phone, or in person, survey questionnaires are highly structured, carefully constructed measurement instruments that ask respondents the same questions in a uniform way --with allowance made for necessary skip patterns to avoid posing nonsensical or irrelevant questions based on prior responses.

In light of Dr. Steinberg's propensity to use the term "survey" loosely to characterize large *qualitative* inquiries as well as quantitative inquiries, it may be just as important to describe what surveys are <u>not</u>. While surveys may incorporate some open-ended questions to allow respondents to express certain ideas in their own words, surveys do not accommodate customized and nuanced probing, even with the best artificial intelligence built in. Even when conducted in person (and these days, surveys rarely are), surveys afford no latitude for an interviewer to improvise. This disciplined, consistent approach to question structure justifies statistical analysis – and makes it legitimate to generalize from the survey sample statistics to a broader population.

By contrast, qualitative research is a process that seeks depth and nuance at the expense of statistical generalization. Qualitative interviews are shaped by a *semi-structured* interview protocol which, by definition, must allow for improvisation and probing based on the particular answers given by respondents in their own words. Qualitative interviews will also reflect stylistic differences among the interviewers who guide the conversation. The implications are that qualitative questioning is not necessarily or consistently uniform and the conversation between interviewer and subject unfolds in varied ways. There is room for techniques that cannot be employed in a "survey" and the standards of data validity can be more permissive in deference to the nature of the process. It does not qualify as survey *measurement*.

Indeed, qualitative research may be done in many settings for many objectives – but no matter how many interviews are conducted in a qualitative study – we do not call it a "survey" as that term is commonly used. Social scientists reserve that word for a type of research whose mission is to count answers for purposes of statistical generalization, and which therefore require a precisely

and tightly constructed measurement instrument. It appears that Dr. Steinberg has had very limited experience with that kind of research.

Most of the principles that qualify a survey as valid for any purpose fall under several broad headings: (1) sampling reliability, which enables us to project from a subset to an entire population; (2) survey validity, which allows us to feel confident we have correctly measured what we set out to measure without introducing bias; and (3) proper statistical analysis, which enables us to characterize the sample in aggregate and draw correct interpretations and conclusions from the data.

It is not clear to me what "rules of the road" were guiding Dr. Steinberg in the design of her "survey" (she failed to articulate any) but survey scientists agree that for a survey to provide an accurate, statistically projectable picture of a population, the following criteria must be met:

- The universe must be properly defined in a way that is relevant to the inquiry, and survey
  participants must be sampled in a way that is appropriately inclusive and unbiased to
  ensure statistical reliability i.e., allowing us to put a confidence interval around the
  findings.
- All questions (and survey materials) must be clearly written; consistently asked; and non-biasing in order for the findings to be deemed *valid* i.e., allowing us to conclude that we have accurately measured what we mean to measure without skewing or distorting the data.
- Appropriate statistics need to be employed, calculations correctly made, and findings properly and contextually interpreted in order to ensure accuracy of the conclusions i.e., allowing us to use survey numbers to paint a meaningful picture of the population, not just a numerical picture.

#### B. Overview of Deficiencies in the Steinberg Survey

Surveys can run afoul of these guidelines in a number of ways but most of my objections to Dr. Steinberg's survey fall under the heading of measurement validity and interpretation. The survey is poorly constructed, improperly executed, and riddled with errors known to distort the data. The data have been under-analyzed and misinterpreted through a lens of overt and unapologetic bias.

Any study with these deficiencies cannot help but lead to unreliable and largely self-fulfilling conclusions – even if the data are correctly tabulated – but a study that aims to survey potential plaintiffs in a class action case has special vulnerabilities based on sensitizing context and self-interested participation. In short, Dr. Steinberg's survey has produced very little worth knowing, and nothing that can be relied on for important insight into the population studied.

Research is often hypothesis-driven, and Dr. Steinberg's survey explicitly was. She was specifically hired to put numbers to her hypotheses concerning the traumatic effects and life changes experienced by women receiving care from Dr. Akoda. Being guided by hypotheses is certainly not per se a bad thing, but only so long as care is taken to avoid *creating* the results one aims to measure. Survey measurement, like any tool that relies on the answers to questions, is highly prone to response bias because the act of formulating answers is an interpretive process. Participants are sensitive to signals and assumptions about what researchers might want of them, and these influences can shape their responses in ways both tacit and explicit.

A good survey researcher, no matter how deeply committed to her viewpoints and hypotheses, must do everything possible to guard against response bias in designing her instrument, lest research become an instrument of prophecy fulfillment, not scientific inquiry. Dr. Steinberg's avowed commitment to proving preconceptions, combined with her evident lack of expertise in survey methodology, produced a study afflicted with nearly as many problems as there were survey questions. Chapter III enumerates and illustrates them in detail.

#### III. Specific Deficiencies of the Steinberg Survey

There are numerous ways in which survey questions can specifically fail to meet threshold standards of validity – so many ways, in fact, that it may be easier to write a bad survey than a good one. Survey questions can be unclear or confusing. They can be lacking in precision. They can be priming or biasing (whether intentional or not) in ways that increase acquiescence or plant ideas. They can fail to provide appropriate response options, or those options can themselves be biasing. They can be sequenced in ways that allow early responses or questions to influence responses to questions downstream. In all these ways, and some more besides, Dr. Steinberg (and her associate, Lisa Bain) wrote a bad survey. And because a bad survey still produces *numbers* — however off the mark or meaningless they may be — it is an inherently dangerous thing to rely on. It has the look of something authentic, but the data can be a mirage.

 The Steinberg Survey context was inherently prone to produce certain types of response bias, and there was nothing to mitigate that bias – or even encourage candor and reflection – in the scanty instructions provided to respondents.

The creation of a "survey environment" begins with the invitation to participate and instructions regarding how to take it. The general goal is to encourage participation by creating confidence that data will be treated respectfully and confidentially; to anticipate and minimize technical difficulties in advance; to secure data of good quality by encouraging candor and thoughtfulness; and to discourage respondents from attempting to "please" the researcher with specific kinds of responses.

For instance, in surveys used for forensic purposes, it is routine to advise respondents to pay close attention, feel free to withhold an answer if they are not sure, and avoid relying on the opinions of others. In drafting surveys that require significant recall, care is taken to help respondents find their own way back to past events by establishing clear timeframes and by using techniques to help retrieve accurate memories, not promote false ones.

Most surveys, however, are directed at respondents without serious personal "skin in the game" – i.e., the participants are consumers or voters, not alleged victims or financial stakeholders – and as a rule, most surveys are not dedicated, as this one was, to gathering recollections and emotions experienced before and after a specific event (learning of Dr. Akoda's fraud. This survey invitation was sent by lawyers and represented to participants as necessary "so that we can proceed with your case." Notably, those same attorneys were individuals who had a hand in relaying to them the circumstances surrounding Dr. Akoda's imprisonment and claims regarding his credentials.

Dr. Steinberg is not a survey researcher, but as a psychiatrist, she must have been aware of these potential biasing effects. Rather than making efforts to minimize them, she seems, based on her deposition testimony, to have welcomed them, bringing her own confirmation biases to bear in construction of the survey and analysis of the data. The introductory comments did not encourage respondents to take their time (indeed, respondents were

informed that the survey was unlikely to take more than 10 minutes even though, perhaps, it should have taken more); nor were they given orientation instructions regarding the time frames at issue and the importance of differentiating feelings and experiences *before* versus *after* they learned of the charges against Dr. Akoda. Indeed, a commonly used approach in such surveys is to address time frames separately without segueing back and forth between them to avoid conflation. This survey "time-traveled" at will.

In short, no precautions were taken to foster accurate retrospection or accommodate the possibility of a respondent having had positive experiences with Dr. Akoda. On the contrary, this "survey" was really an instrument for eliciting evidentiary testimony from putative class members in litigation, and in that sense, was a prophecy meant to be self-fulfilling.

 The survey was <u>not pretested</u> with respondents for clarity of content nor for accuracy of programming, despite the sensitivity of the material and the avowed need to accommodate low literacy levels.

A cardinal rule of survey science is the importance of a pretest to ensure not just that survey program mechanics are in working order, but equally important, to confirm that respondents understand the questions and the instructions. A pretest requires that at least five eligible survey respondents be asked to take the survey as they would in their own environment, and then be the subject of what, in survey science, is referred to as a "cognitive debrief". In a cognitive debrief, pretest respondents are encouraged to identify questions or instructions that puzzled or confused them and are also proactively probed for comprehension of key concepts and phrases – either in person or by phone or "Skype". Respondents' screens are typically tracked real-time during the pretest so that the interviewer can observe the answers as they are recorded and then follow up with appropriate debrief questions.

A cognitive debrief is, itself, a qualitative interview, guided by a protocol *developed specifically for the survey at issue* based on potential concerns a research team might have about certain difficult questions and concepts. Surveys often undergo some revisions based on pretest feedback because it is not uncommon for researchers to discover that there are comprehension problems – even with questions they anticipate will be entirely clear. Sometimes a second pretest is needed to confirm the efficacy of revisions. It is considered professionally irresponsible to omit the pretest step – even in the fast-paced world of commercial research, where critical business deadlines and decisions place a premium on rapid turnaround.

Lack of time is no excuse for omitting a pretest, especially when (a) the survey population is understood to include disproportionate numbers of women who are under-privileged, (b) the survey population does not comprise proficient and experienced survey-takers (e.g., a survey panel); and (c) respondents and are being asked highly sensitive questions for purposes of legal adjudication, where validity standards must be all the higher. Dr. Steinberg acknowledges that her aim was to write a survey geared to "third-grade" reading level – and potentially, to low levels of computer literacy as well. It is a rather extraordinary act of hubris for a

researcher to assume she can accomplish that without a pretest, even if she has prior experience interviewing people with that level of reading proficiency. Each survey is different, with different question structures and language, and different instructions for question completion. Researchers need to exercise due diligence by pretesting before they go live, since there is no opportunity for course-correction once the survey is underway.

Had Dr. Steinberg conducted a pretest, she might well have discovered that phrases like "emotional well-being" were not consistently interpreted by respondents, or that respondents did not understand the importance of honoring skip patterns, or that they did not grasp some of her time frame references. She might also have discovered that some of the answer categories she supplied were inadequate to accommodate the range of likely and relevant responses. A researcher who neglects to conduct a pretest runs the risk of making survey errors that would compromise or invalidate the survey altogether.

Dr. Steinberg avoided questions that would have allowed for measurement of
intensity via rating scales, and instead, collected largely binary responses to
questions that were often "stacked" with more than one "yes" option to prompt the
expected or desired answer.

The vast majority of questions in this survey require women to indicate whether they do (did) or do not (did not) have specific reactions or feelings about Dr. Akoda and what symptoms or consequences they have experienced. A prime example is the survey question concerning whether women trusted Dr. Akoda, asked as a simple yes/no question even though trust could be said to reside in a situational context or along an intensity continuum, and is clearly situated at points in time. The word, "trust", is itself a complex idea, with multiple connotations, even in the context of a physician-patient relationship where trust in motivation/care, trust in medical competence, and trust in personal integrity are not necessarily the same things.

Another noteworthy example is the question that asks whether survey participants' experience with Dr. Akoda has affected trust in *doctors generally* (7a). Here, again, just two answer options are offered: "yes, it has led me not to trust doctors" and "no". This is a "textbook" illustration of how <u>not</u> to ask a question. It consistently leads with an affirmative response option and amplifies the "yes" with a single extreme statement that now obliges us to assume that every respondent who gave that response now trusts no physicians at all. The possibility of exercising greater caution, greater attention to credentials or recommendations, or any other nuanced version of "yes" has been effectively excluded by the heavy-handed wording of that answer.

Other survey questions that pursued *impact* (6a-t) are also all yes/no questions but often with a twist: here response options were typically proliferated to accommodate multiple time frames in a way that allowed Dr. Steinberg to offer three "yes" answer options (only before, only after, both) stacked up against a single "no" (Q's 6a-t). The idea of balancing response options so as not to create a positive or negative bias is also survey research canon, since we

know that respondents are statistically more like to select a type of answer option that is offered more frequently than another.

The 6g-s questions on impact also illustrate Dr. Steinberg's focus on an arbitrary time frame to proliferate three "yes" options (past month, prior, both) accompanied (always at the bottom) by a single "no". While bearing no clear relationship to the point at which any of these women learned of problems with Dr. Akoda's credentials, this time frame was nonetheless targeted for measurement over the frequency or intensity of *symptoms*. We don't know from the responses whether those symptoms have been experienced daily or just once, and how intense they may have been — and, of course, we do not know how many women were unsure if they had those symptoms or when since it was not measured (see commentary below). It is also worth noting that this arbitrary last month vs prior timeframe was inserted without warning after a series of time frame questions that focused on before and after learning of the charges against Dr. Akoda. It is poor practice to change question or answer structures in that way without fair warning since people readily develop response habits and often fail to notice changes.

Dr. Steinberg may have stacked the deck even higher by failing to rotate the position of "yes" and "no" responses anywhere. (There is a known bias toward "yes" in many circumstances, especially if it is consistently positioned first.) Indeed, I find no evidence of question or response rotation in any place where it might be considered appropriate, despite the fact that survey software platforms make this a fairly easy operation to perform and the principle of response rotation is routinely honored in all forensic surveys.

 Dr. Steinberg's failure to consistently offer "don't know" or "can't recall" options wherever in the survey they were appropriate violates another cardinal rule of survey design.

If there is a possibility that respondents may not recall or know the answer to a question, or they might conceivably be on the fence about something, the survey researcher needs to provide a response option to accommodate that, since the absence of a "don't know/not sure/can't recall" ("DK/NS") response option has been shown to have demonstrable effects on the results. Binary (yes/no) questions, in particular, need to provide hesitant or fence-sitting respondents with some refuge.

Not *every* survey question requires a DK/NS option (e.g., age and residency, occupation, or routine product purchase) but any question that requires significant recall or complex assessment should allow respondents to take refuge in uncertainty. Otherwise, respondents are forced to provide an answer that does not accurately reflect how they feel or what they recall. The omission sends a signal that respondents *ought* to remember, *ought* to have definite feelings, even if they don't. Uncertainty or hesitation can be made to seem illegitimate.

Dr. Steinberg's survey was comprised extensively of questions requiring recall of events that may have happened years ago, questions involving medical practice, and many other questions about past or current emotions for which respondents did not necessarily have clear answers. Examples include whether they trusted Dr. Akoda, whether they ever felt scared or threatened by him, or whether they were ever made to feel uncomfortable in his presence. Dr. Steinberg did include a don't know or remember option for a number of other similar questions – for example, regarding use of gloves or sexual arousal during an exam, or physical and emotional symptoms diagnosed since their experiences with Dr. Akoda. It is not clear whether she failed to appreciate the basic principle or was merely disinclined to honor it in some places. The absence of a "don't know" or "not sure" option for important questions has, in my experience, been grounds for disqualifying surveys altogether.

That is because survey data that make no provision for "don't know" or "not sure" will overstate the percentage of definitive responses in directions that favor social acquiescence. Respondents who would otherwise have picked a "don't know" or "not sure" response are more likely, when they can't, to choose a response they perceive is socially acceptable or likely to please an interviewer. The implicit bias can be quite powerful – especially for people asked to take a survey that will help attorneys proceed with their case.

There is no clear rationale for when and why Dr. Steinberg offered "know/can't recall/not sure" response options but her suggestion at her deposition that they add time to the survey are, at best, pretextual. The absence of a relevant response option can actually increase response time as respondents struggle to decide in which direction they might want to err.

#### Where Dr. Steinberg supplied substantive answers, the deck was frequently stacked with loaded language and biasing response sets.

A striking example is 5b, which asks respondents how they felt when they heard about the charges against Dr. Akoda. This question would have been better handled as an open-ended one since the number of emotions one might envision would comprise a long list. Instead, Dr. Steinberg chose to offer four negative words ("shocked", "angry", "betrayed", "sad") along with "neutral" – a peculiar term that might better have been expressed as "indifferent"). In that way, she deprived respondents of the chance to express themselves fully from the outset before she had primed them, and she made it more challenging for them to select other words that might have offered us more insight on their own feelings. It is not clear how many respondents actually checked "other" or took the opportunity to specify, but the easy thing for anyone to do was select one of the four negative words already provided. A woman who was mildly disconcerted or incredulous or had some other reaction not captured by Dr. Steinberg's options had to work harder than others to express her point of view.

In much the same way, a question asking why women did not tell anyone about inappropriate things said by Dr. Akoda (4f) provides words like "ashamed" or "embarrassed" but does not offer respondents the option of saying that they were not much bothered by the interactions or they weren't sure they interpreted them correctly, etc.

Another different form of bias can be seen in questions that asked respondents to compare Dr. Akoda's pelvic and breast exams with exams given by other physicians (3a-b). Both questions provided three categories – "positive", "neutral", "negative" – but gratuitously offered examples of the negative (more rough, insensitive, longer, sexual talk and/or touch) to help define it in a suggestive way. There are several things wrong with this pair of questions. First, there should have been no prompts at all in the answer categories about what negative might mean. Second, respondents should have been allowed to explain in their own words what about their personal experience was negative. Trained survey researchers understand the need to be judicious about when and how open-ended questions are utilized, but if ever there were a case for soliciting open-ended responses, this was it. Without benefit of respondent commentary here, we have only the words Dr. Steinberg herself supplied. All other possible interpretations or objections have been ruled out of hand.

In addition, it is well-established that survey respondents take tacit clues from certain aspects of question construction to detect a preferred response to which they should acquiesce. Longer, more fully elaborated responses tend to be favored, just as proliferation of negative responses increases the odds that a negative response will be chosen.

Notably, so too does gratuitous repetition of questions. Regardless of how women responded to Q. 3a, they had another opportunity to indicate whether they found Dr. Akoda's exams more or less *painful* than others in Q. 4c, accompanied this time by a priming statement: "Pelvic exams are never fun, but...". It's not clear what effect this language actually had, if any, but if Dr. Steinberg felt conviction about its value in orienting respondents, Q. 3a would have been the spot in which to introduce it.

• Dr. Steinberg neglected to program skip patterns and did not necessarily use them appropriately, allowing (or sometimes compelling) respondents to answer questions for which they were arguably ineligible.

One of the many boons of on-line surveys is that even the most basic survey software platforms can be programmed to guide respondents through the survey with automated skip patterns. Dr. Steinberg's technical assistant evidently did not avail himself of this option, or at least did not do so consistently, and the hazards are illustrated in the Q. 2 (trust) series.

After a few introductory questions about where they had seen Dr. Akoda and for what purposes, the survey asks respondents in Q. 2a if they trusted Dr. Akoda. This is a fairly stark way of broaching the topic of the "relationship" (as this section is labeled) because it goes straight to the heart of the claims, without allowing respondents to offer a general evaluation of the quality of care they received from Dr. Akoda. As a simple yes/no question, without any clarifying time frame or "don't know" option, it is also a highly *biasing* way of broaching the topic.

It turns out that 79% of respondents said yes to Q. 2a, a finding which Dr. Steinberg couches as *initial* trust – even though nowhere in the question is the word "initial" or a synonym used; the

question is completely non-specific as to timeframe. Respondents who said *yes* were then given a second bite of the apple with a follow-up "If you answered yes to question 2a but at some point began not to trust him, what happened that changed?" The question is highly suggestive.

Things look even worse when we consider the potential reasons offered for ceasing to trust Dr. Akoda: four specific options (rudeness, pain, sexual comments long pelvic exams) topped by the blandly uninformative, "just something about him" (an option chosen by roughly a third of the sample). That curious list is notable for the omission of many plausible reasons for ceasing to trust a physician, which might have included specific advice offered, a failure to respond to calls, medical outcomes, etc. Since the focus was apparently on establishing sexually inappropriate or abusive physical contact as precipitating factors, Dr. Steinberg's response categories were limited to those ideas.

Thanks to that second bite, almost no one could get through this series without ultimately affirming lack of trust in Dr. Akoda. The 79% who trusted him "initially" was reduced to roughly 20% of the sample once respondents had been asked the follow-up (my calculation based on Dr. Steinberg's own reported statistics). By the time respondents reached Q, 2d (ever feel scared or threatened during care, yes/no), they were primed to respond in hyperbolic ways about Dr. Akoda.

Another instance in which the survey conspicuously failed to take advantage of the software to skip responses is 5c, where respondents are asked *if* you are upset about what Dr. Akoda did, why? No attempt was made to exclude people who had given a neutral response in 5b, which meant that virtually everyone was vectored into this question -- even if they were not, in fact, upset. The question offers four reasons (no opportunity to elaborate or say "other") before nodding to the people who should not have been asked this question by providing them with a "not upset" response at the bottom. Dr. Steinberg presumed everyone in the sample was upset, or should have been upset, and here, as elsewhere, the survey means to preordain or prove it.

 While Dr. Steinberg's answer categories were frequently inadequate to the question and/or biasing, she did not provide any analysis of the other-specific responses, depriving us of insight about respondents who were "disenfranchised" by the answer options supplied.

Dr. Steinberg's agenda for the survey was evidenced in close-ended response categories that featured certain themes prominently and excluded others of equal relevance. In most cases, however, respondents appear to have had the option to choose "other" and to specify an answer if they chose to. Unfortunately, the data have not been coded and tabulated.

Surveys tend to ration their reliance on open-end response options, including "other-specify", for various reasons. The need to code verbal responses introduces another step with its own challenges and complications, but we frequently offer an "other-specify" option to spare

respondents the effort of force-fitting themselves into places they don't comfortably belong. Here, especially, the "other-specify" respondents hold special interest, given the answer categories Dr. Steinberg chose to provide.

And, indeed, we have reason to suppose a fair number of respondents did make use of "other", if responses to 1a are any indication. Even when devising a question as apparently benign as the one that asked how patients originally came to Akoda, Dr. Steinberg managed both to proliferate redundant options and miss enough possibilities to produce 24% "other". As a general rule, the appearance of large numbers of "other" responses is a signal that the pre-specified response categories have not been adequate to the job. Thus, even if we begin with no intention of coding those miscellaneous "other" answers, percentages above 20% encourage a review in order to further elucidate the data patterns. There is, however, no evidence that Dr. Steinberg looked at any of the open-ends she collected.

Respondents answering Q. 1c regarding types of visits did *not* have that "other-specify" option, even though her scant three answer categories exclude meaningful possibilities, such as visits for symptoms, fertility, or contraception, among other possibilities. Here, as in many other places, a pretest would have been helpful – to the extent there was actual interest in knowing the answers to this question. It is not clear what use Dr. Steinberg meant to make of it.

Another noteworthy example of a question that might have profited from an "other-specify" option is 5a, concerning how respondents initially learned of the charges against Dr. Akoda. One option conspicuous for its absence is an attorney or someone representing Plaintiffs in the case. This would have been useful information to have in assessing the data.

 While ostensibly geared to a 'third-grade reading level', this survey posed questions which many women of <u>any</u> education or reading proficiency level, much less more challenged respondents, would be hard-pressed to answer.

There is reason to doubt that many women have a clear view of how long a pelvic exam should take – especially since duration of that exam can depend on age, symptomatology, and other reasons for the visit, creating significant variance and equally significant recall challenges. There is also reason to question whether a patient of any education level could necessarily have discerned whether a chaperone was positioned in a place from which she could see the exam, especially when lying prone. People are notoriously poor judges of time and vantage point – and, as Dr. Steinberg so accurately puts it, pelvics are "never fun". They prompt thoughts and emotions of many sorts, including anxiety about the outcome. It is a large leap of research faith to imagine that the answers given by respondents to such questions can be relied on, especially in a general survey context that primed negative responses.

One of the more egregious examples of questions to which no woman could have a reliable answer is the series of questions designed to elicit physical symptoms experienced "as a result of Dr. Akoda's conduct" (6t-6x). Women are not being asked merely whether they have been

diagnosed with high blood pressure but whether they have been diagnosed as a result of those experiences. For starters, anyone who believes she has been diagnosed with one or more symptoms on the list for other reasons has no place to signal that, so every answer here counts against Dr. Akoda as the cause, regardless of whether he was. More important, however, the question boldly presumes that *anyone* (physician or patient) could know whether a diagnosis of high blood pressure or PTSD or "major depressive disorder" was "as a result" of experiences with Dr. Akoda (or revelations about him). This is not a survey population equipped to make that determination or likely to have speculated about it unless prompted to do so. If a respondent perceived a connection, the perception might not be accurate; and whether or not founded, it is quite likely to have been fostered by the experience of taking this survey rather than a product of respondent's own ingoing thought process about experiences of being treated by Dr. Akoda.

Compounding error with bias, Dr. Steinberg asked a single follow-up question about severity for all "your physical symptoms" (of which over a dozen were listed), leaving the respondent to, first, assess whether any symptom might actually qualify as mild/moderate/severe, and then, second, to ponder over how to respond if different symptoms had varying degrees of severity. Failure to provide opportunity for specific reporting creates bias toward "severity" insofar as it invites people to aggregate. Bias aside, it is more vivid evidence of poor survey technique. Data from all these symptom questions should be disregarded.

While intrepid in asking questions that respondents truly could not answer, Dr.
 Steinberg omitted asking some meaningful ones that they could reasonably have been expected to answer, and which would have elucidated their experiences.

It is noteworthy that Dr. Steinberg asked numerous questions about symptoms and life consequences she sought to attribute to experiences with Dr. Akoda but asked nothing about any medical harm they attribute to his care except a question that first built a negative frame ("if you are upset about what Dr. Akoda did, why?") and also failed to ask why they chose to remain in his care.

In an impartial survey of this population, respondents would have been asked at the outset for their assessment of the quality of care they received, any medical consequences they perceived as a result of his care, and even emotional distress linked to those consequences. Some of these lines of questioning would properly have begun as open-ended to enable respondents to express their own opinions and experiences without the biasing effects of Dr. Steinberg's questions. We would have learned whether they switched doctors at any point and why; and if they did not switch, why not. We also would have learned more about the circumstances under which they first heard about Dr. Akoda.

Finally, we could have gained more insight into the demographic backgrounds of these women, including their income status, education, employment, whether they have children (and how many had been delivered by Dr. Akoda). Insurance can be a proxy of sorts for some

demographic measures, but it is far from definitive. There were nearly as many relevant things Dr. Steinberg omitted to ask as *irrelevant* things she chose to include.

The argument that this survey needed to be 10 minutes long lacks credibility. It was not engineered to be especially efficient (for lack of survey design expertise) and while response rate is, in general, influenced by survey length, there is no evidence that response rate among a putative class with a stake in the outcome is so sensitive to length, nor that 10 minutes would be a critical number. Dr. Steinberg could have written a meaningful 15-minute survey that extracted more information. And if she were so concerned about maximizing response rate, she could have checked how many other questionnaires had been completed at any point in her analysis. There is no single number in her report that proves a point, no threshold statistic she has identified as meaningful. Competent data processing could have reached back and integrated "stragglers" into the survey database with ease.

#### Dr. Steinberg's analysis is striking both for its superficiality and its wanton misattribution of causality.

Having had no access to a computerized database, I am going to assume for the moment that the statistics in Dr. Steinberg's report have been correctly calculated. It hardly matters, in any event, because statistical calculations applied to distorted or nonsensical data are not meaningful, even when the math is correct.

It is noteworthy that Dr. Steinberg presented (and quite possibly performed) only a very superficial analysis of the database – and perhaps only some portions of it. There is no evidence that she used cross-tabulation to look at subgroups and establish whether responses were plausibly linked to circumstances and how (ob vs gyn care, length of experience with Dr. Akoda, etc.). These are the sorts of ad hoc analyses that are routinely employed both to develop keen insights and also to establish face validity of the data. (Here, lacking automated skip patterns, we have no way of establishing whether people who answered certain questions had met the relevant conditions of eligibility. We also have no way of linking the kind of behaviors they experienced with the kinds of outcomes or symptoms they report – all relevant to provide a meaningful picture of the sample.)

To the extent that she is made aware of contradictions in the data, Dr. Steinberg's approach is to rationalize, rather than analyze, by invoking the argument that feelings are potentially so complex, one cannot expect consistency. If that theory holds any water, then even a well-done survey may be inappropriate to the task of fully understanding people's experiences and feelings. Surveys are instruments whose measurement validity and quantitative interpretation demands that we make practical assumptions about our ability to tabulate and interpret responses to each question. Response inconsistency may be deemed "data" leading to elucidation in qualitative or clinical evaluations, but it cannot be taken as an indication of measurement "success" or insight in quantitative surveys. It is taken as a sign of measurement error.

Dr. Steinberg's lack of thorough statistical analysis is primarily an error of omission, serious though it may be. Dr. Steinberg's critical error of *commission* is her unjustified (and unscientific) presumption of causality where none can legitimately be assumed. A key example is her insistence on linking physical symptoms and life outcomes to Dr. Akoda based on respondents' own reporting of a link (itself, shaped by lack of knowledge and survey bias) or – worse yet – her assumption that anything negative event reported by this survey population post-Akoda *must* be laid at his doorstep. In any given timeframe, some proportion of people in a population will experience depression, job loss, or a diagnosis of hypertension. Dr. Steinberg makes no attempt to control for that in her analysis, taking on face value both the accuracy of the event reporting and the meaningfulness of respondents' own primed attributions.

In considering how spurious these relationships are likely to be, it is also important to take note of something Dr. Steinberg herself likes to feature: the special psychological vulnerability of this population based on reporting of prior abuse or threat. Unaccountably, the questions that address the topic (series 8) are flagged as highly personal -- no more so, I would argue, than many others that preceded them – and respondents are invited to decline to answer. That, though, is a small point relative to the interpretation she makes of their significance. Dr. Steinberg features prior abuse and threat as a *source of elevated risk* from experiences with Dr. Akoda when, in fact, a history of abuse could quite easily be interpreted as the *source* of whatever sequelae -- including depression or job loss – Dr. Steinberg attributes directly to Dr. Akoda. As survey researchers should know, association is not causality – and, in this case, we cannot be sure what is real association and what is distortion.

In deflecting criticism of bias, Dr. Steinberg points to the fact not everyone in the sample agrees with everything or reports every adverse outcome – in other words, not all respondents have been influenced by the circumstances of the survey (evident self-interest) or the design of the questions to acquiesce. There is a substantial degree of diversity in responses, suggesting considerable heterogeneity of experience, emotions, and ostensible outcomes, but for Dr. Steinberg, there should be cold comfort in that. The idea that not everyone was led by survey bias to the same responses neither validates the data nor precludes the likelihood that some or many were. It is hard to imagine a survey so successful in engineering false acquiescence that every single respondent, or even necessarily half, can be led to "yea-say." There is too large a corpus of study confirming the effects of survey bias to dismiss the issue. And indeed, the challenge of measuring its effects is what makes survey bias so insidious. You cannot easily measure them without deliberate experimentation or cross-study comparison, but you can legitimately assume they are present.

Under the heading of unanalyzed data, I point finally to the many open-ended commentaries provided by survey participants that describe their experiences with Dr. Akoda and their emotional responses to those experiences. I understand that Dr. Steinberg has not chosen to code and tabulate them but, rather, to offer them as a form of narrative. The difficulty is that the reporting in some of them appear to have face validity or interpretability (allowing a

patient to go into "shock" on the examining table and "ripping open" her clitoris) while others are confused or confusing accounts of obstetrical care that seem, in instances, unrelated to Dr. Akoda. There is anger and complaint, to be sure, but not all of it necessarily rings true or fair. Dr. Steinberg seems to regard herself as primarily a conduit for this outpouring without offering any strategy for interpretation and validation.

 Finally, we need to be cautious in discounting concerns about non-response bias in a survey of putative class members – and to challenge the premise that these results would be statistically generalizable, even if the survey were properly conducted.

The sample size studied appears large enough to represent the universe of potential class members. The question we need to ask is whether it is representative enough. Survey research as a discipline and the applied fields in which it is used (from polling to market research) are forced routinely to consider non-response bias and sampling reliability. The general public is sometimes made aware of these issues when the accuracy of political polling numbers comes into focus but while non-response bias almost looms over us, survey researchers are largely forced to behave (apply statistics and make interpretations) "as if" non-response bias were not an issue – however optimistic or unjustified that may be.

In this case, however, we are looking at a very particular kind of survey universe and a very particular source of potential non-response bias, insofar as women who chose not to respond may include disproportionately large numbers of patients who do not feel aggrieved. I call out this concern less to add yet another criticism of Dr. Steinberg's methodology than to flag a legitimate intellectual challenge. I don't know enough about how the sampling frame was developed by the attorneys to offer commentary on what systematic bias may have been introduced or not but even if there had been no systematic sampling bias, we cannot rule out significant non-response bias based on self-selection.

All that said, it almost doesn't matter. Regardless of whether self-selection is an actual problem here (i.e., in the event that non-responders over-represented women may have expressed no interest in joining the class or expressed interest but ultimately opted out of the survey), the data from those who were surveyed cannot be put to obvious use because the survey measurement instrument employed was, itself, so seriously flawed. Repeated mismeasurement generates untrustworthy statistics.

#### IV. Conclusions

Dr. Annie Steinberg is undoubtedly an accomplished professional in her own field, but she is not an accomplished practitioner of survey research. It may have seemed to her that her skill in conducting qualitative interviews and general experience in clinical research would have conferred some survey research credentials by casual exposure, but it did not. Survey research is a distinct discipline and skillset, and anyone who develops survey data for forensic purposes needs to have mastered it. Even when hypothesis-driven, it needs to honor principles of measurement integrity and proficiency. Dr. Steinberg's methodologically flawed and overtly biasing survey did not.

As a clinician, Dr. Steinberg has approached the very idea of survey research in a way that reflects her own distinct background. She approached it as a vehicle for eliciting data and testimony from women whom she believes to have suffered serious harm at the hands of Dr. Akoda – including PTSD – although she disclaims any intent to diagnose women individually or the class as a whole. With that mission in mind, she regarded any signal of grievance or harm – no matter how extracted from survey respondents – as "data" merely because she asked many people the same questions in the same ways using a computer program designed to conduct "surveys".

This was *not*, however, an impartial survey meant to fully understand a particular population of women. It was a survey meant to prove a point in any way possible. There are many sources of data and ways for an advocate to prove a case in litigation, but the survey research science should not be pressed into service – and misappropriated – for those purposes. What Dr. Steinberg has proffered as survey research is neither high-quality survey research (as survey scientists understand it), nor testimony that has been subjected to cross-examination or critical interpretation.

The problem with poorly constructed, biased survey is that every single number comes into question. We cannot know how far from reality, or validity, each number is. We know only that there are grounds to doubt them all and no available mechanism for measuring how far off they really are. The sample size might imply that the confidence intervals around these numbers is small but, in reality, problems with the survey methodology would suggest that the confidence interval is ultimately irrelevant.

While we can't necessarily attach reliable numbers or percentages to key issues pursued in Dr. Steinberg's research, what we *take* from her survey is that this sample of putative plaintiffs is diverse in many ways – with respect to their experiences, their impressions, and their reactions. Not all have been harmed and not all have been affected -- or affected in the same ways. Beyond that, conclusions are difficult to draw.

\* \* \* \* \*

Susan Schwartz McDonald

October 14, 2019

## Appendix A







As CEO of **NA**XION, and leader of the firm's Healthcare practice, Susan is a marketing strategist whose areas of expertise include demand forecasting and product optimization, pricing, market segmentation, brand positioning and portfolio strategy. She is known for her marketing ingenuity and her track record in guiding commercialization of paradigm-changing technologies that require new market models, including some of the industry's most important global brands. Other sectors in which she has extensive experience include OTC pharmaceuticals and consumer products – both packaged goods and technology-driven categories.

As a respected expert on brand marketing, Susan also directs the Litigation Support practice of **NA**XION. In that context, she is frequently called upon to conduct surveys and testify as a marketing methodology expert in cases pertaining to trademark confusion, secondary meaning, patent infringement, brand dilution, and deceptive advertising. The focus of her work in that area is often the process of brand development and the factors promoting strong, distinctive brand identity.

Much of Susan's 35-year marketing career was spent at Booz•Allen & Hamilton, a worldwide management and technology consulting firm, of which she was a Vice President for over five years. She lectures and writes frequently on marketing issues and market research techniques, and has contributed to medical journals as well as marketing texts. Susan is also coauthor of a standard text on qualitative research methods, *The Group Depth Interview: Principles and Practice* (Simon & Schuster/Prentice Hall). Her early professional years were spent as a journalist and a poet, contributing regularly to a number of major magazines and newspapers, including *National Review* and *Harper's*.

Susan is the 2011-2012 Past Chair of the CASRO Board of Directors, the trade association of the US marketing and survey research industry, recently renamed The Insights Association. Currently, she is a trustee of The Wistar Institute, the world's oldest incubator of biomedical discoveries in cancer and immunology, and a member of the Advisory Board to the marketing research program of the Rutgers University Graduate School of Business. She is also President of the Board of the Chamber Orchestra of Philadelphia.

Susan holds M.A. and Ph.D. degrees from the Annenberg School for Communication, University of Pennsylvania, where she was trained in communications theory and social psychology. Her B.A. was awarded magna cum laude, Phi Beta Kappa, from Smith College.

## SUSAN SCHWARTZ McDONALD MARKETING PUBLICATIONS

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### SUSAN SCHWARTZ McDONALD TESTIMONY/DEPOSITION ACTIVITY SUMMARY

(2013 - Present)

Serenity Pharmaceuticals, LLC, et al., Counterclaim-Plaintiffs v. Ferring B.V., et al., Counterclaim Defendants

U.S. District Court for the Southern District of New York

C.A. No. 1:17-cv-09922 (RWS), ECF Case

Deposition on behalf of Counterclaim-Plaintiffs (November 27, 2018)

J-B Weld Company, LLC, Plaintiff v. The Gorilla Glue Company, Defendant U.S. District Court for the Northern District of Georgia Atlanta Division

Case No. 17-CV-03946-LMM

Deposition on behalf of Plaintiff (July 10, 2018)

Forever 21, Inc., Plaintiff v. Gucci America, Inc., et al., Defendants U.S. District Court of California, Western Division Case No. 2:17-cv-04706-FMO-E Deposition on behalf of Defendants (June 28, 2018, New York)

MARS, Incorporated, et al., Plaintiffs v. The J.M. Smucker Company, et al., Defendants U.S. District Court for the Eastern District of Virginia Alexandria Division No. 1:16-cv-1451 (CMH/MSN)

Deposition on behalf of Defendants (July 12, 2017, Philadelphia)

Deposition on behalf of Defendants (July 12, 2017, Filliadelphia)

Adidas America, Inc., et al., Plaintiffs v. TRB Acquisitions, LLC, et al., Defendants U.S. District Court, District of Oregon Portland Division No. 3:15-cv-02113-SI

Deposition on behalf of Defendants (May 31, 2017, Philadelphia)

Pinterest, Inc., Plaintiff v. Pintrips, Inc., Defendant U.S. District Court for the Northern District of California No. CV 113-04608-PS-KAW Deposition on behalf of Defendant (January 14, 2015, Philadelphia) Testimony on behalf of Defendant (May 26, 2015, San Francisco)

In the Matter of Investigation: Certain Footwear Products U.S. International Trade Commission No. 337-TA-936

Deposition (May 21, 2015, Washington, DC)

HM Electronics, Inc., Plaintiff v. R.F. Technologies, Inc., Defendant U.S. District Court, Southern District of California No. CV12-2884-BAS (MDD)

Deposition on behalf of Defendant (November 24, 2014, Philadelphia)

OraLabs, Inc., Plaintiff v. The Kind Group LLC, Defendant U.S. District Court for the District of Colorado Civil Action No. 1:13-cv-00170-PAB-KLM Deposition on behalf of Defendant (July 24, 2014, Philadelphia)

Healthcare Royalty Partners, L.P. (f/k/a Cowen Healthcare Royalty Partners, L.P.), Plaintiff v. Shionogi Inc., LLC, Defendant Supreme Court of the State of New York, New York County Index No. 650424/2012

Deposition on behalf of Plaintiff (June 18, 2014, New York)

Zest IP Holdings; Zest Anchors, LLC, Plaintiffs v. Implant Direct Mfg., LLC; Implant Direct LLC; Implant Direct International, Defendants U.S. District Court, Southern District of California No. 10-0541 LAB (WVG)

Deposition on behalf of Plaintiffs (June 3, 2014, Chicago)

T-Mobile US, Inc., T-Mobile USA, Inc. and Deutsche Telekom AG, Plaintiffs v. Aio Wireless LLC, Defendant U.S. District Court for the Southern District of Texas, Houston Division Civil Action No. 4:13-cv-2478

Deposition on behalf of Plaintiffs (October 21, 2013, Philadelphia)